Food and Drug Administration, HHS

(2) The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle 3¾ inches wide and 2¼ inches high:

IMPORTANT—ELECTRONIC PRODUCT RADIATION WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36-point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in 36-point Gothic Condensed type.

- (3) Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for mailings other than those required by this part.
 - (c) The notification shall be sent:
- (1) By certified mail to purchasers of the product and to subsequent transferees
- (2) By certified mail or other more expeditious means to dealers and distributors
- (d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

- (a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.
- (b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.

Subpart D—Exemptions From Notification Requirements

§ 1003.30 Application for exemption from notification requirements.

- (a) A manufacturer may at the time of giving the written confirmation required by \$1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to \$1003.11(a), apply for an exemption from the requirement of notice to the persons specified in \$1003.10(b).
- (b) The application for exemption shall contain the information required by §1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

§ 1003.31 Granting the exemption.

- (a) If, in the judgment of the Secretary, the application filed pursuant to §1003.30 states reasonable grounds for an exemption from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.
- (b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with §56.104 or